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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,409	02/22/2002	Norman E. Cameron	P-0281576/Z7	2660

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[REDACTED] EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
1614	16

DATE MAILED: 12/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/889,409</b>	Applicant(s) <b>Cameron et al.</b>
Examiner <b>Kevin E. Weddington</b>	Art Unit <b>1614</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Sep 6, 2002

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 22, 24, 25, and 42-48 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 22, 24, 25, and 42-48 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 and 9

6)  Other: \_\_\_\_\_

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Claims 22, 24, 25 and 42-48 are presented for examination.

Applicants' preliminary amendments and information disclosure statement filed February 22, 2002; and the information disclosure statement filed February 28, 2002 have been received and entered.

Applicants' election filed September 6, 2002 in response to the restriction requirement of June 6, 2002 has been received and entered. The applicants elected the invention described in claims 22, 24, 25 (Group I) with traverse. Newly added claims 42-48 will be examined with the elected invention.

*Claim Rejections - 35 U.S.C. § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 24, 25 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (JR) in view of Hirai et al. (MR) further in view of Budavari et al. (R).

Hirsch et al. teach HMG-CoA reductase inhibitors for the normalization of vascular endothelial dysfunction. Note page 2, liens 1-14 states the HMG-CoA reductase inhibitors may reduce the effects of vascular endothelial dysfunction that may contribute to microvascular complications of diabetes. Clearly the cited reference teaches HMG-CoA reductase inhibitors inherently treat diabetes and its complications in the absence to the contrary.

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred HMG-CoA reductase inhibitor (hereby known as the statin drug) disclosed in claim 22. However, the secondary reference, Hirai et al., teaches the applicants' preferred statin drug as an old and well-known drug possessing the same activity as the HMG-CoA reductase inhibitors of the primary reference, Hirsch et al. Clearly one skilled in the art would have been motivated to substitute one HMG-CoA reductase inhibitor (statin drug) for another HMG-CoA reductase inhibitor and achieve the same effects in the absence of evidence to the contrary.

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The instant invention differs from the cited references in that the cited references do not teach the addition of other drugs used for to treat diabetes or the complications of diabetes as disclosed in claims 25, 43 and 44. However, the tertiary reference, Budavari et al., teaches pioglitazone (a well-known insulin sensitizing agent) is used to treat diabetes. The applicants are merely combining two individually known drugs used to treat diabetes or the complications of diabetes into a single composition to achieve an additive effect in the absence of evidence to the contrary.

The instant invention differs from the cited references in that the cited references do not teach the applicants' specific dosage range of the statin drug (HMG-CoA reductase inhibitor). However, the determination of a dosage having optimum therapeutic index is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum amounts to get the maximum effect of the statin drug (HMG-CoA reductase inhibitor).

Claims 22, 24, 25 and 42-48 are not allowed.

The references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner K. Weddington whose telephone number is (703) 308-1235.

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*K.E. Weddington*  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington

December 18, 2002